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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/955,657	09/18/2001	Richard E. Wooley	U022 1020.1	1163

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CHRISTENSEN, O'CONNOR, JOHNSON, KINDNESS, PLLC
1420 FIFTH AVENUE
SUITE 2800
SEATTLE, WA 98101-2347

EXAMINER	
YOUNG, MICAH PAUL	
ART UNIT	**PAPER NUMBER**
1618	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/955,657	WOOLEY ET AL.	
	Examiner	Art Unit	
	MICAH-PAUL YOUNG	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 June 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,5-15,18-22 and 56-62* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,5-15,18-22 and 56-62* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/20/08 has been entered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claims 1, 2, 5-8, 10, 11-15, 18, 21, 22, 56-62 rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Fischetti et al (USPN 6,423,299 hereafter '299) in view of Viegas et al (USPN 5,958,443 hereafter '443). The claims are drawn to a method of

inhibiting the proliferation of a bacterial infection in a skin injury by applying a topical formulation comprising a chelating agent and an antibacterial agent.

2. The '299 patent disclose a method of inhibiting the proliferation of bacterial infections in various locations including burns and oral mucosa (abstract, claims, col. 8, lin. 12-35), wherein a composition comprising a chelating agent and an active antibacterial formulation is applied to the injury (claims, examples, col. 9, lin. 62-col. 10, lin. 5). The chelating agent includes ETDA (claims 5) and the antibacterial agents include neomycin erythromycin, minocycline, tetracycline, and others in a concentration from 0.5-10% (col. 9, lin. 19-28). The chelating agents are included in such a way as to synergistically enhance the other components in the formulation (col. 11, lin. 30-32). The formulation comprises phosphate buffers that regulate the pH of the formulation from 5.5-7.5 (col. 7, lin. 55-60). The bacterial infections that are treated with the formulation include both Gram negative and positive bacterium such as Pseudomonas and Staphylococcus (col. 3, lin. 43-47, col. 4, lin. 15-20). The formulation includes carriers such as gel-forming polymers and thickening agents (col. 8, lin. 41-col. 9, lin. 12). The reference, though disclosing the synergistic relationship of the chelating agents to the rest of the formulation is silent to the specific concentration. Also the reference discloses a different buffering agent. The inclusion of a specific buffer compound in a wound treatment formulation is well within the level of skill in the art as seen in the '443 patent.

3. The '443 patent discloses a topical wound healing composition comprising chelators such as EDTA (col. 11, lin. 18-20), antimicrobial agents such as tetracycline and amikacin (col. 10, lin. 20-22), along with buffers such as phosphate and tromethamine (TRIS) which maintain the pH of the formulation at 7.4 (col. 11, lin. 35-55). The drugs are present in a concentration from

0.1-60% (col. 11, lin. 28-31), while the buffer is present in a concentration of as much as 5%, which is sufficient to maintain the pH at 7.4 (col. 11, lin. 50-60). The formulation can be applied to wounds as a second skin that delivers active agents tot eh affected site (col. 5, lin. 1-5). It would have been obvious to include the buffer agents of the '446 patent into the formulation of the '299 patent since they both describe topical wound healing formulation comprising similar chelators, antimicrobial agents and buffering agents.

4. Regarding the specific concentration of the chelator compounds it is the position of the Examiner that such limitation in view of the prior art are obviated since the general conditions of the claims have been met by the prior art. It is the position of the Examiner that the concentration of chelators is merely an optimizable limitation as long as synergy is maintained. In each embodiment of the '299 patent synergy is maintained. Applicant is reminded that where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *See* In re Aller, 220 F.2d 454 105 USPQ 233, 235 (CCPA 1955).

5. Furthermore the claims differ from the reference by reciting various concentrations of the active ingredient(s). However, the preparation of various compositions having various amounts of the active is within the level of skill of one having ordinary skill in the art at the time of the invention. It has also been held that the mere selection of proportions and ranges is not patentable absent a showing of criticality. *See* In re Russell, 439 F.2d 1228 169 USPQ 426 (CCPA 1971).

6. Regarding the claims limitation reciting the identification of a bacterial infection, determining the MIC and concentrations of the chelators and antibacterial agents, it is the

position of the Examiner that such limitation are inherent to any treatment method and would be obvious to any artisan of ordinary skill. These steps are basic treatment steps and would be encompassed in the routine practice of the invention of the '299 and '433 patents. These steps are merely a recitation of inherent procedures practiced by every artisan of ordinary skill in the field of bacterial infections and do not impart patentability to the claims.

7. With these things in mind it would have been obvious to follow the suggestions and teachings of the prior art in order to provide an improved method of treating bacterial infections. The artisan of ordinary skill would have been motivated to combine the chelating concentration of the '979 patent into the treatment method of the '299 in order to maintain the synergistic properties of the components and improve the treatment of the infection. One of ordinary skill in the art upon combining these teachings, suggestions and disclosures would have expected a treatment method suitable for the disinfecting surface injuries.

8. Claims 1,2,5-15,18-22 and 56-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Fischetti et al (USPN 6,423,299 hereafter '299), Viegas et al (USPN 5,958,443 hereafter '443) and Cuny et al (USPN 6,207,679 hereafter '679). The claims are drawn to a method of treating specific injuries.

9. As discussed above the combination of the '299 and '443 patent provides a method of treating bacterial infections in the skin by combining chelating agents, antibacterial agents and carriers in a synergistic combination. Burns are disclosed in the '299 patent as well as infections in the respiratory system, oral and vaginal mucosa. The reference is silent to ulcers, scrapes,

bruises, and lesions. These injuries can also be treated in a similar fashion as disclosed in the '679 patent.

10. The '679 patent teaches the use of antimicrobial agents in the treatment of infections (bacterial/fungal) in wounds such as burns, ulcers, scrapes and bruises (abstract, col. 34, lin. 40-55). The formulations can be used to sterilize medical devices or treat bacterial or fungal infections on internal mucosa, both orally and vaginally (*Ibid.*). Formulations include solutions, elixirs and mouthwashes (col. 38, lin. 46-57). The formulation is effective against both Gram-positive and negative bacterial genus such as *Pseudomonas* and *Staphylococcus* (col. 32, lin. 17-39). The formulation comprises various antimicrobial agents such as penicillins, amino glycosides, and cephalosporins along with carriers and chelators such as EDTA (col. 36, lin. 7-16; col. 38, lin. 19-20). A skilled artisan would have been motivated by these teachings to administer the formulation of the '299 and '433 combination to the skin for wound treatment as taught by '679.

11. With these things in mind one of ordinary skill in the art would have been motivated to follow the teachings of '679 to combine biocidal compounds such as those found in both '679 and '299 in order to treat Gram-positive or negative bacterial infections. The '299/'443 combination teaches the importance of a synergistic relationship between the chelator and the biocide, while the '679 teaches the varying methods of application. The minimum inhibitory concentration (MIC) for each compound would be known by one of ordinary skill in the art as shown in the '679 patent. It would have been obvious to follow the suggestions of '299/'443 combination in order to topically treat bacterial infections with an expected result of a method of treating infected wounds.

Response to Arguments

Applicant's arguments, see Remarks, filed 6/20/08, with respect to the rejection(s) of claim(s) 1, 2, 5-15, 18-22 and 56-62 under 103(a) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of 103(a) over the combined disclosures of Fishcetti et al, Viegas et al and Cuny. Applicant argued that the previous rejection comprising Raad was nonanalogous art and unrelated to wound healing. This is overcome by the newly cited art Viegas et al which discloses a topical wound healing composition comprising antimicrobial agents, chelators and pH buffers. The reference is silent to synergy, however the buffers are present in an amount to maintain the pH of the composition within the ranges of the instant invention. Thus, the same result must occur. Also, applicant has not show synergy or show it in a manner that is commensurate in scope with the claims.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICAH-PAUL YOUNG whose telephone number is (571)272-0608. The examiner can normally be reached on Monday-Friday 7:00-4:30; every other Monday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

/MICAH-PAUL YOUNG/
Examiner, Art Unit 1618